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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,939	05/13/2002	Michael Schwager	1001.1591101	4760

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EXAMINER	
MARMOR II, CHARLES ALAN	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 08/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,939	SCHWAGER, MICHAEL	
	Examiner	Art Unit	
	Charles A. Marmor, II	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5 and 8-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5 and 8-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed March 5, 2004. The Examiner acknowledges the amendments to the specification; the amendments to the drawings; the amendments to claims 1-3, 5, 8, 9, 12 and 15; the cancellation of claims 4, 6 and 7; and the addition of new claim 16. Claims 1-3, 5 and 8-16 are pending.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-3, 5, 8, 9, 11, 15 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Rosenthal et al. ('903). Rosenthal et al. teach a guiding aid for an instrument to be advanced within a vascular system (see Fig. 1A). The guiding aid includes a flexible shapeable shaft **10** including a distal tip **12**; a first bent section having a first curvature K_1; a second bent section proximal to the first bent section having a second curvature K_2; a first axis **21** extending

from the distal tip along a straight line in the direction in which the distal tip is pointing; a straight intermediate section between the first and second bent sections with a second axis along the straight intermediate section; a straight proximal section **15,18** with a third axis along the straight proximal section; and an angle α_1 between the first axis and the second axis and an angle α_2 between the second axis and the third axis. The two bent sections of the shaft have the same sign of curvature and are located in substantially the same plane. Both angle α_1 and angle α_2 are obtuse angles, having a range of possible angles including those between 120° and 150° (see column 3, lines 1-10). The radius of the first curvature K_1 may selected to be smaller than the radius of second curvature K_2. A straight end section is disposed distal of the first bent section extending along axis **21**. The two bent sections are substantially in the shape of a circular arc. A helically wound coil (spring) may be located around at least a part of the shaft in order to reinforce the shaft and facilitate flexibility and torqueability (column 6, lines 56-58 and 64-67). The total bend in the shaft is between 60° and 120° (approximately 90° in Figure 1A). Radiopaque means **24** are provided in the region of the distal tip of the shaft.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenthal et al. ('903) in view of Hassett ('018). Rosenthal et al., as discussed hereinabove, teach all of the

limitations of the claims except that the shaft is tapered toward its distal end. Hassett teaches a guiding introducer system having a tubular shaft that is tapered toward its distal end in order to a good transition with a good transition with an instrument that is guided through the shaft (see at least column 8, lines 65-67). It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to provide the shaft of a guiding aid similar to that of Rosenthal et al. with a taper toward its distal end in view of the teachings of Hassett in order to form a good transition with a dilator or other instrument that is guided through the tubular shaft.

7. Claims 12, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenthal et al. ('903) in view of Abrams et al. ('089).

Regarding claims 12, Rosenthal et al., as discussed hereinabove, teach all of the limitations of the claim except that a helically wound spring with a distal end having a rounded terminal element is disposed around at least a part of the shaft. Abrams et al. teach that a superelastic guiding member including a tubular shaft and a helically wound spring coil with a distal end having a rounded terminal element disposed around at least a part of the tubular shaft that assists in visualization of the guiding member within the body and reduces trauma to the body lumen. It would have been an obvious design choice to one having ordinary skill in the art at the time Applicant's invention was made to form the tubular shaft of a guiding aid similar to that of Rosenthal et al. with a helically wound spring coil having a rounded terminal element disposed around at least a part of the tubular shaft in light of the teachings of Abram et al. in order to assist in the visualization of the guiding member within the body and to reduce trauma to the body lumen.

Regarding claims 13 and 14, Rosenthal et al., as discussed hereinabove, teach all of the limitations of the claims except that the shaft is made of superelastic nitinol. Abrams et al. teach that it is known in the art of tubular guiding members to form the shaft of a material having superelastic characteristics, such as nitinol, in order to facilitate advancing the guiding member in a body lumen while minimizing the risk of damage to the body lumen (see at least column 11, lines 20-31). It would have been an obvious design choice to one having ordinary skill in the art at the time Applicant's invention was made to form the shaft of a guiding aid similar to that of Rosenthal et al. of superelastic nitinol in view of the teachings of Abrams et al. in order to facilitate advancing of the guiding member in a body lumen and minimize the risk of damage to the body lumen during advancement therein.

Response to Arguments

8. Applicant's arguments with respect to claims 1-3, 5 and 8-16 have been considered but are moot in view of the new ground(s) of rejection. Applicant contends that Weinstock et al. fail to disclose a shaft with two bends where both of the angles that are formed are obtuse because the guidewire shaft of Weinstock et al. has one obtuse angle and one acute angle. Applicant further contends that Berg et al. fail to disclose a shaft with two bends where both of the angles that are formed are obtuse because the guiding device shaft of Berg et al. has one obtuse angle and one acute angle. While the Examiner does not concede the persuasiveness of Applicant's arguments, these arguments are now moot in new grounds of rejection citing Rosenthal et al. set forth hereinabove. The guiding aid of Rosenthal et al. more clearly reads on the limitations of

Applicant's amended claims in that the shaft has two bends where both of the angles that are formed are obtuse.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Charles A. Marmor, II
Primary Examiner
Art Unit 3736

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August 25, 2004